Final 2026 Clinical Lab Fee Schedule Indicates a 47% Increase in Payment Determination for the Category I CPT Code for OGM use in Hematologic Malignancies

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SAN DIEGO, Dec. 03, 2025 (GLOBE NEWSWIRE) -- Bionano Laboratories, a wholly-owned subsidiary of Bionano Genomics, Inc. (Nasdaq: BNGO) offering CLIA-certified laboratory developed tests (LDTs) based on optical genome mapping (OGM), announced today that the clinical lab fee schedule (CLFS) for 2026 posted by Centers for Medicare & Medicaid Services (CMS) indicates an increase of 47%, from $1263.53 to $1853.22, for the payment for the Category I Current Procedural Terminology (CPT®) code 81195. This code applies to use of OGM in cytogenomic genome-wide analysis to detect structural and copy number variations related to hematologic malignancies, or blood cancers.

CMS previously established a payment determination, effective January 1, 2025, for the Category 1 CPT code 81195 at $1263.53 based on a crosswalk to an existing code. A request for reconsideration and crosswalk to a different code with a higher payment rate was made. The clinical diagnostic laboratory test (CDLT) committee that reviews such applications voted unanimously in favor of the proposed crosswalk by a vote of 10-0 with no abstentions. CMS subsequently agreed with the panel and the OGM users who commented as part of the process and re-priced code 81195 to $1853.22, effective January 1, 2026.

CPT codes for OGM are key components for obtaining reimbursement from third party payers for the OGM-based LDTs developed by Bionano Laboratories and used as alternatives to legacy cytogenetics methods such as karyotyping, fluorescence *in-situ* hybridization (FISH) and microarrays. There are now two such codes, 81195 for use of OGM in hematologic malignancy analysis and 81354 for use of OGM in constitutional genetic disease. Bionano Laboratories has offered OGM-Dx™ HemeOne, OGM-Dx™ Postnatal Whole Genome SV and OGM-Dx™ Prenatal Whole Genom SV, all of which would be expected to be covered by these two codes.

“We believe the increase in the CLFS for the Category 1 CPT code 81195 will make it easier to offer OGM-based LDTs for hematologic malignancies due to the potentially more favorable reimbursement from payers,” said Alka Chaubey, chief medical officer of Bionano. “We believe the newly established payment level, which is substantially higher than the original pricing, is appropriate for the additional data collection, interpretation and reporting needed when using OGM for blood cancers. We also believe that establishing Category I CPT codes can raise the awareness of the utility and support for OGM in the oncology and clinical genetic testing communities, not only in the United States, but around the world as well.”

About Bionano Laboratories:

Lineagen, Inc. d/b/a Bionano Laboratories provides access to genetic answers and support utilizing cutting-edge technologies to advance the way the world sees the genome. Its clinical diagnostics services offer optical genome mapping (OGM) testing that combines a comprehensive testing portfolio with thoughtful and accessible support options. Bionano Laboratories also offers direct access to OGM for applications across basic, translational and clinical research. For more information, visit www.bionanolaboratories.com

About Bionano

Bionano is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company’s mission is to transform the way the world sees the genome through optical genome mapping (OGM) solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. The Company also offers an industry-leading, platform-agnostic genome analysis software solution, and nucleic acid extraction and purification solutions using proprietary isotachophoresis (ITP) technology. Through its Lineagen, Inc. d/b/a Bionano Laboratories business, the Company also offers OGM-based diagnostic testing services.

For more information, visit www.bionano.com or www.bionanolaboratories.com

Unless specifically noted otherwise, Bionano’s products are for research use only and not for use in diagnostic procedures.

Forward-Looking Statements of Bionano Genomics

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. Words such as “anticipate,” “believe,” “can,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and are intended to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things; the ability and utility of the Category I CPT code to drive use and adoption of our OGM-based tests; the ability of the OGM-Dx tests to obtain coverage and reimbursement; whether the Category I CPT code will ultimately be important for clinical OGM testing; the ability of OGM to outperform legacy cytogenomic methods; our expectations regarding product uptake, revenue, flowcell usage by customers we consider to be routine users of OGM, market development and OGM adoption, including as evidenced through publications highlighting the utility and applications of OGM, our commercial prospects and future financial and operating results; continued research, presentations and publications involving OGM, its utility compared to traditional cytogenetics and our technologies; and our ability to drive adoption of OGM and our technology solutions and any other statements that are not of historical fact. Each of these forward-looking statements involves risks and uncertainties. Accordingly, investors and prospective investors are cautioned not to place undue reliance on these forward-looking statements as they involve inherent risk and uncertainty (both general and specific) and should note that they are provided as a general guide only and should not be relied on as an indication or guarantee of future performance. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks and uncertainties associated with: the failure of the Category I CPT code to drive use and adoption of our OGM-based tests; the failure of our tests to obtain coverage and reimbursement; the failure of the Category I CPT code to prove to be important for clinical OGM testing; the failure of OGM to

outperform legacy cytogenomic methods; the timing and amount of revenue we are able to recognize in a given fiscal period; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts and our ability to continue as a “going concern,” which requires us to manage costs and obtain significant additional financing to fund our strategic plans and commercialization efforts; the risk that if we fail to obtain additional financing we may seek relief under applicable insolvency laws; the impact of adverse geopolitical and macroeconomic events, such as the ongoing conflicts between Ukraine and Russia and Israel and Gaza and uncertain market conditions, including inflation, tariffs, and supply chain disruptions, on our business and the global economy; general market conditions; changes in the competitive landscape and the introduction of competitive technologies or improvements to existing technologies; changes in our strategic and commercial plans; the ability of medical and research institutions to obtain funding to support adoption or continued use of our technologies; study results that differ or contradict the results mentioned in this press release; the risk that we are not able to complete a strategic transaction that would increase stakeholder value; and the risks and uncertainties associated with our business and financial condition in general, including the risks and uncertainties including those described in our filings with the Securities and Exchange Commission (“SEC”), including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2024, our Quarterly Reports on Form 10-Q and in other filings subsequently made by us with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise, except as may be required by law.

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